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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/782,841 | 02/14/2001 | Merrill A. Biel | 22,272-19 | 1618 |

7590

06/17/2003

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EXAMINER

DAVIS, MINH TAM B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 06/17/2003

1642

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782,841

Applicant(s)

BIEL, MERRILL A.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/05/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7,8,10,12-15 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7,8,10,12-15 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 1-3, 5, 7-8, 10, 12-15, 45, species i.v. administration of an adjuvant(s) after the administration of photodynamic light therapy, administration of an immune modulator after the administration of photodynamic light therapy, and administration of a photosensitizer agent proximate to the primary tumor site are examined in the instant application.

The following are the remaining rejections.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH

Claims 7-8 remain rejected under 35 USC 112, second paragraph, pertaining to the use of the trademark name in the claims, for reasons already of record in paper . No:11.

Applicant amends the claims to recite DETOX brand adjuvant.

Rejection remains, because claims 7-8 still recite the trademark name DETOX.

REJECTION UNDER 35 USC 103

Claims 1-3, 5, 7-8, 10, 12-15, 45 remain rejected under 35 USC 103 as being obviousness over Bellnier, DA, 1991, J Photochem. Photobiol, B: Biol, 8: 203-210, in view of US 4,96,3354, Krosi et al, 1996, Cancer Res, 56(14): 3281-6, Canti G et al, 1994, Anti-Cancer Drugs, 5: 443-447, Sakurai et al, 1989, Vaccine, 7(3): 269-74, Malik,

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A et al, 1993, Infect Immunol, 61(12): 5062-6, Matsumoto, Y et al, 1991, Intl J Cancer, 49(3): 444-449, and Kim et al, 2000, Vaccine, 18: 597-603, for reasons already of record in paper No:11.

Applicant argues that Bellnier et al do not teach or suggest a tumor cell specific immunological response resulting in metastatic tumor eradication initiated via an administration of an immunologic adjuvant and photodynamic therapy at a primary tumor.

Applicant argues that the eradication of the local tumor taught by Krosi et al is not via a systemic immune response. The adjuvant of Krosi et al is administered to increase the local macrophage level to effect the local uptake of the photosensitizing agent by the tumor. Applicant argues that Krosi et al teach away from the invention, by warning that systemic administration of high doses of GM-CSF may lead to profound perturbations in hemopoiesis and induce serious side effects.

Applicant argues that Canti et al teach passive specific tumor cell immunity against subsequent reintroduced identical tumor cells. Applicant argues that Canti et al do not teach or suggest the formation of a metastatic tumor specific immune response targeted against metastatic tumor cells existing within the living body at the time of photodynamic therapy as presently claimed. Applicant argues that Canti et al merely identifies a particular recognized need that it would be advantageous if the metastasized or undestroyed cancer cells could be eliminated immunologically rather than through chemotherapy.

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Applicant recites Lunch et al and Musser et al, arguing that some photodynamic therapies induce immunosuppression, whereas some others induce immunopotentialiation.

Applicant argues that there is no reasons, suggestion or motivation found in the prior art whereby a person of ordinary skill in the art would make the combination of the cited references by achieve the subject matter of the present claims.

Applicant's arguments in paper No: 13 have been considered but are found not to be persuasive for the following reasons:

The recitation of Lunch et al and Musser et al is acknowledged. The references by Lunch et al and Musser et al however could not be examined because it seems that they are missing in the response.

Although Bellnier et al do not specifically teach or suggest that photodynamic therapies produce a tumor cell specific immunological response,,Canti et al cure the defect of Bellnier et al. Canti et al teach how to perform photodynamic therapies for inducing strong anti-tumor specific immunity. Further, Canti et al provide motivation for treating metastatic or primary cancer cells that are not destroyed by photodynamic therapy, by a combination therapy using photodynamic therapy in combination with an adjuvant, taught by Bellnier et al or Krosi et al, because Canti et al teach that photodynamic therapy alone often incompletely destroys the neoplastic mass, and therefore it would be advantageous if the metastasized and undestroyed cancer cells could be eliminated immunologically rather than through chemotherapy.

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One would have expected that an adjuvant, such as TNF, G-CSF, or monosaccharide type adjuvant, or DETOX adjuvant, as taught by Bellnier et al, US 4,963354, Sakurai et al, Malik et al, and Matsumoto et al, when administered i.v. would increase non-specific immunity systemically, and boost the induction of antibodies against antigens, because these are the inherent properties of adjuvants, as taught by US 4,963354.

One would have expected that the combined method taught by Bellnier et al would eliminate primary cancer cells that are not destroyed by photodynamic therapy and metastatic tumors, due to a combination of a strong specific immune response produced by photodynamic therapy, as taught by Canti et al, which is further enhanced by adjuvants, as taught by US 4,963354, wherein the adjuvants produce in addition a non-specific systemic immunity when administered intravenously, which is known to be effective in treating metastatic cancer cells, as taught by Sakurai et al, and Matsumoto et al.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

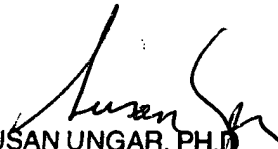
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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.


SUSAN UNGAR, PH.D.
PRIMARY EXAMINER

MINH TAM DAVIS

June 13, 2003